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SECTION 9
510(K) SUMMARY

FOI RELEASABLE

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation chooses to submit a summary of information respecting safety and effectiveness.

- COMMON/USUAL NAMES: Retrieval Basket, Mechanical Lithotripter
- TRADE/PROPRIETARY NAME: The tradename of the device has not been finalized.
- CLASSIFICATION NAME &
DEVICE CLASSIFICATION: Class II

Name	Number	21 CFR Ref.
Biliary Mechanical Lithotripter	78 LQC	876.4500
Biliary Stone Dislodger	78 LQR	876.5010

- DEVICE PANEL/BRANCH: Gastroenterology-Urology (GU)
Urology/Lithotripsy (ULDB)
- OWNER/OPERATOR: Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760
Owner/Operator No. 9912058
- CONTACT PERSON: Daniel J. Dillon, Senior Regulatory Affairs Specialist

INDICATIONS FOR USE

The Lithotripter-Compatible Basket is indicated for the retrieval of stones from the biliary system and endoscopic crushing (lithotripsy) of biliary calculi. The Lithotripter-Compatible Basket should not be used for any purpose other than its intended application.

CONTRAINDICATIONS

None known.

COMPLICATIONS

Possible complications that may result from endoscopic crushing (lithotripsy) and retrieval of biliary calculi include, but may not be limited to: stone impaction; perforation; hemorrhage; hematoma; septicemia/infection; pancreatitis; cholangitis; allergic reaction to contrast medium.

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the Lithotripter-Compatible Basket is substantially equivalent to the currently-marketed Monolith Mechanical Lithotripter. Figure 9-1 compares the descriptive characteristics of these products.

PERFORMANCE CHARACTERISTICS

Laboratory testing regarding characteristics was performed on Lithotripter-Compatible Basket to verify its safety and performance. A biocompatibility assessment was performed on the patient- and fluid-contact materials of the Lithotripter-Compatible Basket with satisfactory results.

PACKAGING, STERILIZATION, AND PYROGENICITY

The Lithotripter-Compatible Basket will be packaged in a PVC tray and placed inside a Tyvek-Mylar pouch. The Lithotripter-Compatible Basket will be sterilized using ethylene oxide gas using the AAMI protocol for ethylene oxide sterilization. Pyrogenicity testing will be performed on a periodic basis to monitor bacterial endotoxin levels.

CONCLUSION

Boston Scientific Corporation believes that Lithotripter-Compatible Basket is substantially equivalent to its currently-marketed Monolith Mechanical Lithotripter and Biliary Helical and Mini-Helical Baskets. Figure 9-1 compares the descriptive characteristics of these products. As demonstrated in Figure 9-1, the Lithotripter-Compatible Basket is equivalent in its indications for use, while being very similar in design and materials. In addition, Boston Scientific Corporation has presented laboratory testing and biocompatibility information. The information presented provides assurance that the Lithotripter-Compatible Basket will meet the minimum requirements that are considered acceptable for its intended use.

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FIGURE 9-1: SIMILARITIES AND DIFFERENCES BETWEEN LITHOTRIPTER-COMPATIBLE BASKET, MONOLITH MECHANICAL LITHOTRIPTER, AND BILIARY HELICAL AND MINI-HELICAL BASKETS

	<i>Lithotripter-Compatible Basket (This 510(k))</i>	<i>Monolith Mechanical Lithotripter (K943191)</i>	<i>Biliary Helical and Mini-Helical Baskets (K925495)</i>
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USE

<i>Indication</i>	Biliary stone retrieval, crushing and removal	Biliary stone crushing and removal	Biliary stone entrapment and removal
<i>Route of Administration</i>	Endoscopic	«— Same	«— Same

BASKET

<i>Dimensions</i>	5.5 x 2.5 cm 4 x 2 cm 3 x 1.5 cm	«— Same	22 - 37 mm (Length) 8.5 - 20 mm (Diameter)
<i>Number of Wires</i>	4	«— Same	3 - 5
<i>Shape</i>	Octagonal	«— Same	Helical
<i>Material</i>	Stainless Steel	«— Same	«— Same

SHEATH

<i>Diameter</i>	2.3 mm	«— Same	0.63 - 1.6 mm
<i>Length</i>	180 cm	«— Same	35 -240 cm

HANDLE

<i>Mechanism</i>	Three-Ring, Detachable	Trigger, Non-Detachable	Three-Ring, Non-Detachable
<i>Injection Port</i>	Present	Present	Present